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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,952	10/03/2000	Stephen H. Friend	215538-00401	7342

7590 04/30/2004

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EXAMINER	
HORLICK, KENNETH R	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/678,952	FRIEND ET AL.	
	Examiner	Art Unit	
	Kenneth R Horlick	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12,15,17,18,21,22 and 24-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 12, 15, 17, 18, 21, 22, and 24-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 2, 3, 5-8, 16, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are confusing because it cannot be determined what is encompassed by a "homolog thereof, or an analog thereof" with respect to a gene. Specifically, while this language is discussed briefly on page 6 of the specification, only examples of what might be encompassed are given, and it is unclear what "certain sequences or domains" and "similar functions" refers to.

2. With respect to the above rejection, the arguments of the response filed 02/13/04 on pages 7-8 have been fully considered, but are not found persuasive. While the response points to definitions on pages 5-6 and examples on pages 22-23 of the specification, the Office maintains its position that these only present limited guidance in determining what might be considered a "homolog" or "analog", and thus one of ordinary skill in the art cannot in fact determine whether or not a given gene with a certain amount of "similarity" of structure or function is encompassed in the claims.

3. Claims 2, 3, 6, and 9-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While claim 1 is drawn to a method

of screening for or identifying a secondary target site such as a *tol* gene, the rejected claims all depend on such a site already being identified and available. Despite the recitation on page 4 of the specification that "...mutations in three recessive yeast genes tol1, tol2, tol3 (telomerase overexpression lethal) have been identified that render unviable host cells with an overexpressed tolomerase gene TLC1...", there is no physical description whatsoever as to what these genes are. Lacking such a description, one of ordinary skill in the art would not find the inventors to be in possession of any such secondary target site or tol gene. Consequently, the inventors were clearly not in possession of: the methods of claims 9-12 which require using such a site; the site of claim 13 and the lethal mutations thereof of claim 14; the methods of claims 15-18 which require a drug which interacts with a gene product associated with such a site; the pharmaceutical composition of claims 19 and 20 which require such a drug; the cell of claim 21 which requires such a site; the method of claim 22 which requires a cell having a known tol gene; the site of claim 23; the methods of claims 24 and 28 which require use of said drug; nor the pharmaceutical compositions of claims 25-27, 29 and 30 which require said drug. In PTO Tech. Center 1600, such claims as these are sometimes called "reach-through", as they encompass subject matter which has not yet been attained by the inventors, but might possibly be attained at some future time with further work/research. Thus, of the pending claims, applicants were only in possession of the screening method by which such sites or tol genes might be identified (claims 1, 4, 5, 7, and 8).

4. With respect to the above rejection, the arguments of the response on pages 8-10 have been fully considered, but are not found persuasive. The Office maintains its position that applicants were only in possession at the time of filing the application of the invention as claimed in claims 1, 4, 5, 7, and 8, drawn to methods of identifying a secondary target site, using a known primary gene encoding telomerase activity. The rejection states that the claims at issue all depend on a secondary site already being identified and available, yet the specification does not disclose any such secondary site actually identified by the method of claim 1. Thus, it is still concluded that the rejected claims are clearly "reach-through" type claims as discussed above.

5. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method using yeast cells, does not reasonably provide enablement for any type of cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to carry out the invention commensurate in scope with these claims.

In Ex parte Forman, 230 USPQ 546 (Bd. App. 1986), the Board considered the issue of enablement in molecular biology. In considering these factors: (a) in order to practice the invention, the practitioner must carry out the method using any type of cell; (b) the specification provides guidance with respect to yeast cells; (c) working examples are presented with respect to yeast cells; (d) the invention is directed to screening methods for identifying a secondary target site in relation to an overexpressed telomerase gene using any kind of cells; (e) the prior art teaches genetic screening

involving lethal mutations in yeast cells; (f) the level of skill in molecular biology is high; (g) the results of experiments involving various cell types are not predictable; (h) the claims are broadly drawn, reciting any possible cell type. Based on the above analysis, one of ordinary skill in the art would be subject to undue experimentation in carrying out the claimed methods using any cells except for yeast.

6. With respect to the above rejection, the arguments of the response on page 11 have been fully considered, but are not found persuasive. It appears that the rejection has been misconstrued; as shown above, the rejection argues that claims 1-12 are enabled only for the method insofar as yeast cells are used. Thus the response does not properly state the basis of the rejection, nor does it traverse the particular issue of scope of enablement which is raised.

7. Claims 1-10, 12, 15, 17, 18, 21, 22, and 24-30 are free of the prior art, but are rejected for other reasons. No claims are allowable. Regarding claims 1-12, no prior art has been found teaching or suggesting screening methods comprising: providing cells overexpressing a telomerase activity; effecting a mutation(s) in the genome of the cells at one or more secondary sites; selecting cells having at least one mutation that proves lethal; and determining the site in the genome at which the lethal mutation is located.

8. In reply to the request at the bottom of page 11 of the response, it is acknowledged that the Revocation of Power of Attorney and Appointment and Certification under 37 C.F.R. 3.73 filed 08/06/03 has been received and scanned into the official IFW record.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kenneth R. Horlick, Ph.D.

Kenneth R Horlick
Primary Examiner
Art Unit 1637

04/20/04